

November 4, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.74

Subject: Preparation and Distribution of Sterile Diluent

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum provides guidelines concerning the production and distribution of Sterile Diluent under 9 CFR 112.3, 112.6, and 113.54.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.74 dated May 21, 1985.

III. BACKGROUND

The Center for Veterinary Biologics (CVB) does not consider Sterile Diluent to be a veterinary biological product; however, licensees must provide the proper amount of Sterile Diluent with each licensed veterinary biological product when diluent is required for rehydration or dilution of the product. APHIS specifies the requirements for Sterile Diluent for licensed veterinary biological products in 9 CFR 112.3 and 112.6 (packaging and labeling) and in 9 CFR 113.54 (production and testing). This memorandum provides further guidance concerning the production of Sterile Diluent in USDA-licensed veterinary biologics production facilities and in unlicensed facilities.

IV. GUIDELINES

A. Diluents For Licensed Products

1. *Production in Licensed Establishments* - Licensees may prepare Sterile Diluent in USDA-licensed establishments according to 9 CFR 113.54.

2. *Production in Unlicensed Facilities* - Unlicensed facilities may produce Sterile Diluent for use with licensed veterinary biological products provided:

a. The Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) inspects the diluent manufacturer's facilities and finds them to be acceptable to produce Sterile Diluent,
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b. The licensee or applicant files an Outline of Production describing the diluent manufacturer's procedures for production of Sterile Diluent with the Center for Veterinary Biologics-Licensing and Policy Development (CVB-LPD),

c. The diluent manufacturer gives CVB-IC the authority to inspect their production facilities and all records of production and testing at any time,

d. The licensee files copies of the diluent manufacturer's records of production and testing of each serial at the licensed establishment,

e. For each serial, the licensee conducts all tests specified in the Outline of Production, including a test to ensure that such Sterile Diluent is compatible with its product(s), in licensed facilities,

f. Diluent manufacturers ship each serial of Sterile Diluent required to be packaged and shipped with the final container(s) of licensed biological product(s) to the licensed establishment for testing, finishing, and distribution, and

g. Diluent manufacturers label, package, and ship Sterile Diluent authorized to be packaged and shipped separately from the final container(s) of the licensed veterinary biological product as specified in 9 CFR 112.6(d) and:

(1) Meet all conditions in items a. through e. above,

(2) For each Sterile Diluent, file with CVB-LPD an Outline of Production or Special Outline that provides a complete description of all procedures and conditions,

(3) Provide for sample selection, label accountability, and inventory control adequate to ensure compliance with the regulations and the outline requirements, and

(4) Provide copies of pertinent shipping invoices for the licensed establishment to file with its records of each serial of biological product.

B. Diluents for Other Purposes

1. *Regulatory Authority* - The Center for Veterinary Biologics does not regulate Sterile Diluents produced for purposes other than use with licensed veterinary biological products; however, other authorities may regulate such diluents.

2. *Conditions for Production* - Licensed establishments may prepare Sterile Diluents not intended for use with veterinary biological products in USDA-licensed facilities, provided such diluent labels:

- a. Do not contain the U.S. Veterinary Biologics Establishment License Number, and
- b. Do not contain recommendations or directions for use with licensed veterinary biological products.

/s/ Thomas E. Walton for

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Deputy Administrator
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